



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
[www.uspto.gov](http://www.uspto.gov)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/537,217	11/18/2005	Masaomi Tajimi	RCK-40	2662
35969	7590	10/10/2007	EXAMINER	
JEFFREY M. GREENMAN BAYER PHARMACEUTICALS CORPORATION 400 MORGAN LANE WEST HAVEN, CT 06516			O DELL, DAVID K	
ART UNIT		PAPER NUMBER		
1625				
MAIL DATE		DELIVERY MODE		
10/10/2007		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Interview Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/537,217	TAJIMI ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	David K. O'Dell	1625	

All participants (applicant, applicant's representative, PTO personnel):

(1) David K. O'Dell.

(3) Paul Howard.

(2) Rita Desai. 

(4) David Madge & Jason Chumney.

Date of Interview: 02 October 2007.

Type: a) Telephonic b) Video Conference  
c) Personal [copy given to: 1) applicant 2) applicant's representative]

Exhibit shown or demonstration conducted: d) Yes e) No.

If Yes, brief description: \_\_\_\_\_.

Claim(s) discussed: All.

Identification of prior art discussed: \_\_\_\_\_.

Agreement with respect to the claims f) was reached. g) was not reached. h) N/A.

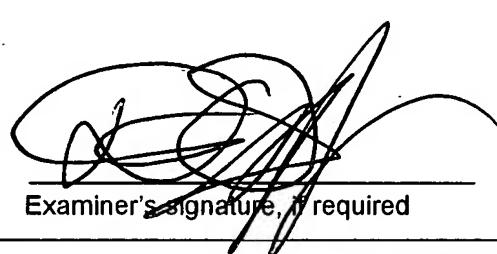
Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: See Continuation Sheet.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN A NON-EXTENDABLE PERIOD OF THE LONGER OF ONE MONTH OR THIRTY DAYS FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.



Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.



Examiner's signature, if required

Continuation of Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: The applicant's took issue with the outstanding office action, primarily with the rejection under 112 1st paragraph for enablement. The examiner had the applicant clarify the meaning of some of the terms for substituents and various terms that were rejected under 112 2nd paragraph. With regard to the enablement rejection for the compounds on how to make, the applicant's defended the prophetic syntheses and stated that the required starting materials for the scope of the claims were available, and that no technical problems existed. They offered to submit as part of the record the location of such starting materials to support these claims. The primary issue that remained unresolved with respect to the compounds was the identity of the substituents R2 and R3 in claim 1. The examiner continued to maintain his position based on the rejections of record, that the full scope (the "3-8 membered saturated heterocyclic ring optionally interrupted by one or two atoms selected from the group consisting of oxygen, sulfur and nitrogen") was not enabled. With respect to claim 4 being rejected under enablement, the examiner notified the applicant that this claim was improperly rejected on that basis and save for the double patenting rejections was allowable if placed in proper independent form. In regards to the claims drawn to the treatment (claims 19-26), the applicant's were of the opinion that the claims were fully enabled based on the prophetic assays of the specification. The examiner pointed to the rejections of record and the scientific documents relied upon therein to show the general lack of predictability of animal models and the poor correlation of in-vitro cell based assays with treatment. While a long list of prophetic animal studies were included in the specification, when asked by the examiner where the data for the compounds of the instant claims could be found in the specification no response was received. However, Mr. Madge said that these compounds were tested, although he did not point out in which assays or which compounds. The examiner acknowledged that TRPV1 antagonists were valid therapeutics for pain and upon verification of the data alluded to by Mr. Madge, the compounds would likely be enabled for the treatment of pain. With respect to the other diseases, namely COPD and urological disorders, the examiner maintained his position for the reasons of record .

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK," on the paper recording the substance of the interview along with the date and the examiner's initials.

### Examiner to Check for Accuracy

Examiners are expected to carefully review the application's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

Name of applicant	Application Number (Series Code and Serial Number)	the form provides for recording of the following information:
Name of examiner	Date of interview	Name of interviewee (telephone, video-conference, or personal)
Name of participants (applicant, attorney or agent, examiner, other PTO personnel, etc.)	An indication whether or not an exhibit was shown or a demonstration conducted	An identification of the specific prior art discussed
Type of interview (telephone, video-conference, or personal)	An indication whether or not an exhibit was shown or a demonstration conducted	An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may not reflect further action by the examiner to the contrary).
Note: Agreement as to allowability is tenable attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tenable attachment of the examiner who conducted the interview (if Form is not an attachment to a signed Office action).		

It is less responsible for the attorney to record the substance of an interview of witnesses.

The section of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself

All businesses with the Patent or Trademark Office should be registered in writing. The basic elements of applications to the Patent and Trademark Office are necessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attorney will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or dispute.

In every instance where recognition is requested in view of an interview with an individual, a complete written statement of the reasons presented at the interview as well as the action taken by the applicant. An interview does not remove the necessity for reply to claims action as specified in § 111, 113, 35 U.S.C. 132.

<sup>37</sup> See Code of Federal Regulations (CFR) § 1.133 Interviews.

A application whether or not an agreement with the examiner was reached at the interview.